

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/297,648 | 03/10/00 | WILLIAMS | 2300-1481C1P |

027476
CHIRON CORPORATION
INTELLECTUAL PROPERTY - R440
P.O. BOX 8097
EMERYVILLE CA 94662-8097

HM12/1002

| EXAMINER |
|-----------|
| BRUSCA, J |

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1631 | 20 |

DATE MAILED: 10/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/297,648 | WILLIAMS ET AL. | |
| | Examiner | Art Unit | |
| | John S. Brusca | 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22, 24-31, 33-40, 42-49, 51-58, 60-67, 69-76, 78-85, 87-94, 96-103 and 105-131 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13, 16</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 22,24-31,33-40,42-49,51-58,60-67,69-76,78-85,87-94,96-103 and 105-131.

DETAILED ACTION

Priority


1. The amendment received 04 June 2001 places the claim for priority under 35 U.S.C. 120 in the proper format in the first sentence of the specification.

Specification

2. The objection to the specification in the Office action mailed 29 November 2000 is withdrawn in view of the amendment received 04 June 2001 inserting missing page 638 into the specification.

3. The applicants have filed a paper containing pages alleged to have been inserted into the specification during the international stage of prosecution of this national stage application. Inspection of International Publication WO 99/38972 reveals that pages 591-594 are different from the instant application, and that the requested insertion of pages 591-594 would cause a deletion of the information on the instant originally filed pages 591-594, and result in two occurrences of Table 21, the first resulting from the requested insertion of replacement pages 591-594, and the second Table 21 from the originally filed pages 634-637. The requested substitution of pages 131, 132, 638-642, and 648-652 would not appear to result in a change in the content of the instant specification. The requested substitution of pages 643-657 would appear to result in a change in the content of the instant specification. The insertion of the substitute pages has been held in abeyance until such time that the applicants clarify the reasons for the insertion of the substitute pages.

Claim Rejections - 35 USC 101 and 112

4. 35 U.S.C. 101 reads as follows:
- 

Art Unit: 1631

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. The rejection of claims 41, 49-57, 59, 86, and 95 under 35 U.S.C. 101 because the claimed invention lacks patentable utility in the Office action mailed 29 November 2000 is withdrawn in view of the cancellation of claims 41, 50, 59, 86, and 95 and the arguments presented in the Amendment received 04 June 2001, and the Declaration of Filippo M. Randozo and George F. Lamson under 37 CFR 1.132 also received 04 June 2001. The papers received 04 June 2001 establish that SEQ ID NO:739 is differentially expressed in tumor cells and therefore has utility as a diagnostic agent.
6. Claims 40, 42-48, 58, 60-66, 85, 87-94, 96-102, and newly filed claims 114, 116, 119, 120, 124, 126, 129, and 130 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility for reasons of record in the Office action mailed 29 November 2000.
7. Applicant's arguments filed 04 June 2001 have been fully considered but they are not persuasive. The applicants state that sequences that are not differentially expressed in tumor cells have utility, but no specific and substantial utility for SEQ ID NOS: 329, 1186, 1938, and 1998 (to which the rejected claims are drawn) are proposed by the applicants in their comments.
8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
9. The rejection of claims 41, 49-57, 59, 86, and 95 under 35 U.S.C. 112, first paragraph because the claimed invention lacks patentable utility in the Office action mailed 29 November 2000 is withdrawn in view of the cancellation of claims 41, 50, 59, 86, and 95 and the arguments


Art Unit: 1631

presented in the Amendment received 04 June 2001, and the Declaration of Filippo M. Randozo and George F. Lamson under 37 CFR 1.132 also received 04 June 2001. The papers received 04 June 2001 establish that SEQ ID NO:739 is differentially expressed in tumor cells and therefore has utility as a diagnostic agent.

10. Claims 40, 42-48, 58, 60-66, 85, 87-94, 96-102, and newly filed claims 114, 116, 119, 120, 124, 126, 129, and 130 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

11. The rejection of claims 25, 34, 43, 52, 61, 70, 79, 88, 97, and 106 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention in the Office action mailed 29 November 2000 due to a defective deposit of a biological strain is withdrawn in view of the Declaration of Carol L. Francis under 37 CFR 1.132 received 04 June 2001 which perfects the deposit of biological strains.

12. Claims 22, 24-31, 33-40, 42-49, 51-58, 60-67, 69-76, 78-85, 87-94, 96-103, and 105-131 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record in the Office action mailed 29 November 2000. This is a written description rejection.



Art Unit: 1631

13. Applicant's arguments filed 04 June 2001 have been fully considered but they are not persuasive. The applicants state that they have disclosed two species of the claimed genus of polynucleotides, however the asserted two species appear to be identical in that the deposited strains comprise the same sequence as the disclosed SEQ ID NOS. The applicants point to the issuance of U.S. Patent No. 5,861,248 as allegedly conflicting with the above stated rejection. Notwithstanding any issuance of a U.S. Patent that might be construed as being in conflict with the above rejection, the Office guidelines for compliance with the written description requirement of 35 U.S.C. § 112, first paragraph (available at www.uspto.gov) will be enforced. The applicants argue that prior court decisions upon which the Office guidelines rely were only relevant to the "dark ages" of molecular biology, however the applicants have failed to provide convincing reasoning as to how the instant specification provides an adequate written description to the full scope of the claimed genus of polynucleotides. It is not apparent how advances in molecular biology techniques subsequent to court decisions upon which the Office guidelines rely result in an adequate description of sequences for which there is no description in the instant specification. The applicants have added newly filed product by process claims 122-131 for which there is not adequate written description. The applicants are directed to the following passages of the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph, "Written Description" Requirement (Federal Register Vol. 66, No.4, 1/5/01, pages

1099-1111

(6) Comment: One comment disagreed with the statement in an endnote that "the fact that a great deal more than just a process is necessary to render a product invention obvious means that a great deal more than just a process is necessary to provide written description for a product invention." The comment indicated that the statement is overly broad and inconsistent with the "strong presumption that an adequate written description of the claimed invention is present when the application is filed." As an extreme case, for example, for product-by-process claims, nothing else would be needed to provide the written description of the product. Response: The endnote has been clarified and is now more narrowly drawn. However, there is no per se rule that disclosure of a process is sufficient to adequately

Art Unit: 1631

describe the products produced by the process. In fact, *Fiers v. Revel* and *Eli Lilly* involved special circumstances where the disclosure of a process of making and the function of the product alone did not provide an adequate written description for product claims. Even when a product is claimed in a product-by-process format, the adequacy of the written description of the process to support product claims must be evaluated on a case-by-case basis.

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed.¹¹ However, the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention.¹² The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art.¹³ This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function.¹⁴ A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.¹⁵

⁵² See, e.g., *Fiers v. Revel*, 984 F.2d at 1169, 25 USPQ2d at 1605; *Amgen.*, 927 F.2d at 1206, 18 USPQ2d at 1021. Where the process has actually been used to produce the product, the written description requirement for a product-by-process claim is clearly satisfied; however, the requirement may not be satisfied where it is not clear that the acts set forth in the specification can be performed, or that the product is produced by that process.

Thus it is clear that the Office policy is that merely claiming a composition in a product by process format does not relieve the applicants from the duty of providing adequate written description of the claimed product.

Claim Rejections - 35 USC § 102

14. The term “degenerate variant” appearing in several of the claims appears in the specification on page 3, line 3, and has been interpreted broadly to mean any sequence variant. For this reason the rejections listed below have been maintained.

15. The rejection of claim 23 under 35 U.S.C. 102(a) as being anticipated by GenBank Accession Number AA444267 in the Office action mailed 29 November 2000 is withdrawn in view of the cancellation of claim 23 in the amendment received 04 June 2001.

16. The rejection of claims 32, 41, 50, 59, 68, 77, 86, 95, and 104 under 35 U.S.C. 102(b) as being anticipated by GenBank Accession Numbers W94391, H43467, W66607, AA114761,

Art Unit: 1631

HSU36478, HSU14990, HSRNAP14K, RRU48288, and U01137, respectively in the Office action mailed 29 November 2000 is withdrawn in view of the cancellation of the claims in the amendment received 04 June 2001.

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 22, 24, and newly filed 112 are rejected under 35 U.S.C. 102(a) as being anticipated by GenBank Accession Number AA444267 for reasons of record in the Office action mailed 29 November 2000.

19. Sets of claims 31, 33, 40, 42, 49, 51, 58, 60, 67, 69, 76, 78, 85, 87, 94, 96, 103, 105, and newly filed 113-121 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank Accession Numbers W94391, H43467, W66607, AA114761, HSU36478, HSU14990, HSRNAP14K, RRU48288, and U01137, respectively for reasons of record in the Office action mailed 29 November 2000.

20. Applicant's arguments filed 04 June 2001 have been fully considered but they are not persuasive. The applicants have amended the claims to recite longer regions of contiguous nucleotides than that indicated on the lineup comparisons to the cited prior art attached to the Office action mailed 29 November 2000. However the claims recite the phrase "a degenerate variant of" the recited SEQ ID NO and the claim has thus been interpreted broadly to continue to read on the cited prior art sequences.

Art Unit: 1631

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. Sets of claims 26-29, 35-38, 44-47, 53-56, 62-65, 71-74, 80-83, 89-92, 98-101, and 107-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over GenBank Accession Numbers AA444267, W94391, H43467, W66607, AA114761, HSU36478, HSU14990, HSRNAP14K, RRU48288, and U01137, each in view of Yang et al. for reasons of record in the Office action mailed 29 November 2000.

23. Applicant's arguments filed 04 June 2001 have been fully considered but they are not persuasive for the reason that the claims recite the phrase "degenerate variant thereof" as discussed above.

Conclusion

24. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Application/Control Number: 09/297,648

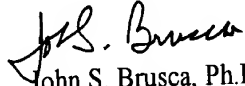
Art Unit: 1631

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca, Ph.D. whose telephone number is (703) 308-4231. The examiner can normally be reached on Monday -Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-5137 for regular communications and (703) 746-5137 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


John S. Brusca, Ph.D.
Primary Examiner
Art Unit 1631

jsb
September 20, 2001